CardinalHealth

Standard Operating Procedure
Pharmaceutical Distribution

DETECTING AND REPORTING SUSPICIOUS ORDERS AND RESPONDING TO THRESHOLD EVENTS

1.0 PURPOSE

1.1 The purpose of this procedure is to provide guidance to Cardinal Health (CAH) employees in the Quality and Regulatory Affairs (QRA) section on responding detecting and reporting suspicious orders, and processing, documenting and making judgments about threshold events, including making decisions about releasing or cutting orders that are suspicious or exceed a threshold.

1.2 The purpose of this procedure is also to comply with or exceed the standards for distributors set forth in the Controlled Substances Act, regulations promulgated pursuant to that Act, and extra-regulatory guidance to which DEA holds distributors responsible.

2.0 SCOPE

This procedure applies when an order is triggered by the CAH's Anti-Diversion Centralization (or equivalent) system for review by the QRA Pharmacist Group in order for the QRA Pharmacist to evaluate the order so as to meet the purpose of the procedure mentioned in 1.0 above.

3.0 REFERENCES / RELATED DOCUMENTS

[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C001.docx"]{- ~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C001.docx" }~~	Daily Threshold Reporting
[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C002.docx"]{- ~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/~~	SOM Threshold Limits

DEFENDANT EXHIBIT
CAH-WV-00740

~~CAD-C002.docx" }~~

4.0 RESPONSIBILITIES

The responsibilities of the QRA Pharmacist team includes

a. Evaluating held orders
b. Identifying suspicious orders
c. Reporting suspicious orders to DEA
d. Performing a detailed review of suspicious orders and orders in excess of customer threshold for the drug family
e. Releasing suspicious orders and orders in excess of customer threshold for the drug family when appropriate
f. Cutting suspicious orders and orders in excess of customer threshold for the drug family when appropriate

5.0 DEFINITIONS

Anti-Diversion Centralization (ADC — The Anti-Diversion Centralization application brings together information for case analysis that currently resides in several computer applications and allows QRA personnel to examine case information in one convenient location and handles actions performed by QRA personnel like cutting, releasing and reporting suspicious orders.

Anti-Diversion Customer Profile — A report generated by QRA containing various background, licensing, and analytical metrics relevant to a customer used to assist in the evaluation of threshold events.

DEA Limit Over Threshold Report — An IT generated report generated by members of IT that contains all threshold events from a specified date.

Threshold Event — The initial held order for a regulated drug which exceeds the threshold set for a specified customer. This is created by a DEA#, Base Code and Threshold Limit combination.

6.0 PROCEDURE

6.1 Initial Review

6.1.1 The following orders are held or cut pending review by QRA under this procedure

a. Orders of interest referred to by a distribution center
b. Orders that exceed a threshold set for the customer for the drug family

6.1.2 In addition, under this procedure, QRA can review other orders that may come to

QRA's attention based on any other criteria.

6.1.3 Under this procedure, QRA must first review EVERY held or cut order under 6.1.1 to determine whether the order is suspicious as that term is used in 21 C.F.R. 1301.74(b). Per the regulation, orders are deemed suspicious if they meet one or more of three criteria:

- **a.** Order is of unusual size
- **b.** Order is of unusual frequency
- **c.** Order deviates substantially from a normal pattern for the customer

6.1.4 Orders that meet one or more of the criteria in 6.1.3 must be reported to the DEA as suspicious.

6.1.5 **Orders of unusual size** are significantly larger than the orders normally placed by the customer or by customers that have a size and type of business that is similar to the ordering customer's business.

6.1.5.1 Orders of unusual size can be as a result of:

- **a.** Unintentional order entry errors (including duplicate order entries)
- **b.** Intentional orders placed by the customer

QRA personnel must use available information and prior experience to determine if the order is an unintentional order entry error or intentional order placed by the customer.

6.1.5.2 Unintentional order entry errors (including duplicate order entries) MUST NOT be reported as suspicious orders to DEA since the customer did not intend to place the order and MUST be cut with no changes to customer threshold and a readjustment of accrual to the level prior to the order entry error.

6.1.5.3 QRA personnel must use available information and prior experience to determine if the order of unusual size is intentional. If QRA personnel determines the order to be intentional and of unusual size then the order is deemed suspicious and MUST be reported to DEA.

6.1.6 **Orders of unusual frequency** are orders that occur significantly more frequently than the orders normally placed by the ordering customer or by customers that have a size and type of business that is similar to the ordering customer's business.

6.1.6.1 QRA personnel can use available information on order history and prior experience on other customers that have a size and type similar to the ordering customer to determine if the order is of unusual frequency.

6.1.6.2 If the QRA personnel determines the order to be of unusual frequency then the order is deemed suspicious and MUST be reported to DEA by QRA.

6.1.7 **Orders that deviate substantially from the normal ordering pattern** are orders that reflect a significant deviation from the customer's normal orders or that deviate substantially from the ordering patterns of customers that have a size and type of business that is similar to the ordering customer's business.

6.1.7.1 Substantial deviations in ordering patterns include, but are not limited to,

a. Orders for an unusually high percentage of controlled substances compared to non-controlled substances
b. Orders for an unusually high percentage of a particular strength of drug that is known or suspected of being widely diverted
c. Other deviations based on QRA personnel's experience

6.1.7.2 QRA personnel can use available information and prior experience on other customers that have a size and type similar to the ordering customer to determine if the order deviates substantially from the normal ordering pattern.

6.1.7.3 If the QRA personnel determines that the order deviates from normal ordering pattern then the order is deemed suspicious and MUST be reported to DEA by QRA.

6.1.8 At the end of 6.1, the customers held or cut order under 6.1.1 will be found in one of the following states.

6.1.8.1 Orders cut due to order entry errors and NOT reported to DEA.

6.1.8.2 Held or cut orders reported as suspicious to DEA.

6.1.8.3 Held or cut orders NOT reported as suspicious to DEA (**e.g.,** a non-suspicious order that exceeded a threshold).

6.1.9 ALL orders reported to DEA as suspicious should undergo Detailed Review Process set forth in 6.3.

6.2 Threshold Event Check on Orders

6.2.1 Any held or cut order under 6.1.1 (whether or not reported as suspicious to DEA) should be checked to see if the order is in excess of the threshold set for the customer for the drug family in the order.

6.2.2 If the order exceeds the threshold set for the customer, the order must be sent for Detailed Review Process set forth in 6.3 (Note that orders reported to DEA as

suspicious have already been assigned to the Detailed Review Process in 6.1.8).

6.2.3 If the order DOES NOT exceed the threshold set for the customer AND the order was not already reported as suspicious to the DEA, the order may be released to the customer using the process set forth in 6.4.

6.3 Detailed Review

6.3.1 Orders assigned for detailed review may arrive from any one of the following sources

a. Orders reported as suspicious to DEA not exceeding thresholds set for the customer
b. Orders exceeding thresholds set for the customer but not reported to the DEA as suspicious
c. Orders reported as suspicious to DEA AND exceeding thresholds set for the customer

6.3.2 The level of review will be determined by the unique facts and circumstances of each matter, including the customer's historical ordering pattern, information in the QRA file about the customer, the context of the order and the facts that are obtained in the early stages of review.

6.3.3 Document the relevant information considered and decision point factors used in the detailed review.

6.3.4 If after completing the steps in detailed review process (6.3) the QRA personnel do not have sufficient evidence to determine that the order is not likely to be diverted into other than legitimate channels the order must be cut using process in 6.5.

6.3.5 If the QRA personnel is unable to conduct the necessary level of detailed review (6.3) due to any reason (including but not limited to non-cooperation from the customer)

a. The order must be cut (6.5).
b. The customer must be referred to the Vice President, Supply Chain Integrity, to determine appropriate course of future action.

6.3.6 If after completing the steps of the detailed review process (6.3) the QRA personnel determines that the order is not likely to be diverted into other than legitimate channels the order may be released using release process (6.4).

6.4 Orders Subject to Release

6.4.1 After initial review process (6.1), if the QRA personnel determines that the order is not suspicious AND the order does not exceed the threshold set for the customer the order can be released.

6.4.2 After the detailed review process (6.2), if the QRA personnel determines that the order is not likely to be diverted the order can be released.

6.4.3 Before the order can be released, QRA personnel must ensure that the reasons for releasing the order and relevant information considered (see 6.3.3) have been recorded.

6.4.4 Determine if the customer's threshold levels should be considered for adjustment following the SOM Threshold Limits ({ HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C002.docx" }{~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C002.docx"~~ }) standard operating procedure.

6.5 Suspicious Orders Not Subject to Release

6.5.1 Cut orders in ADC and leave accrual limiter unchanged.

6.5.2 If the order has already been reported to DEA as suspicious, no additional action is required.

6.5.3 If the order has not been reported to DEA as suspicious (as in the case of orders not deemed suspicious during initial review 6.1, but deemed suspicious after detailed review 6.3), report the order to DEA when the order is cut.

6.5.4 The customer whose order has been cut and reported to DEA as suspicious must be referred to the Vice President, Supply Chain Integrity to determine appropriate course of future action, if in the professional judgment of the QRA personnel, the suspicious order raises concerns about the customer's ordering, distributing and/or dispensing of controlled substances.

6.5.5 Report suspicious order to other regulatory bodies as required.

7.0 DOCUMENTATION REQUIREMENTS

None

CardinalHealth

Standard Operating Procedure
Pharmaceutical Distribution

DETECTING AND REPORTING SUSPICIOUS ORDERS AND RESPONDING TO THRESHOLD EVENTS

Approvals					
Approvals on file in the Pharmaceutical Distribution Corporate Document Center Approvers: Michael Moné				Owner: Christopher Forst PDCDC Coordinator: Jason Paul Snouffer	
Change History					
DCN	Effective Date	Change Type	Training Required	Document Applicability	Training Assignment(s)
2962	12 Apr 2012	Scheduled Review	Yes	Corporate	Other
Other (specify)					
Training assignments to Corporate Anti-Diversion personnel who are involved in the detecting and reporting suspicious orders and responding to threshold events procedure.					
Change Description and Justification					
Scheduled review. Complete Rewrite of entire document to properly define the process for detecting and reporting suspicious order and responding to threshold events. Updated document to coincide with PDQRA formatting criterion.					